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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/008,722	12/06/2001	Kei Roger Aoki	16952CON1DIV5CIP1	5741

7590 02/24/2004  
Stephen Donovan  
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EXAMINER

GUPTA, ANISH

ART UNIT PAPER NUMBER

1654

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/008,722	Applicant(s) AOKI ET AL.	
	Examiner Anish Gupta	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 1-14-04.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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The restriction requirement, dated 10-7-03, has been vacated. The office action dated, 9-30-03, has been reinstated. Applicants response, dated 1-14-04, brought forth the confusion and set forth a response to the outstanding office action of 9-3-03. This response has been considered and the arguments have been addressed below.

### *Estoppel*

#### §1.658 Final Decision:

(c) A judgment in an interference settles all issues which (1) were raised and decided in the interference, (2) could have been properly raised and decided in the interference by a motion under §1.633 (a) through (d) and (f) through (j) or §1.634, and (3) could have been properly raised and decided in an additional interference with a motion under §1.633(e). A losing party who could have properly moved, but failed to move, under §1.633 or 1.634, shall be estopped to take ex parte or inter partes action in the Patent and Trademark Office after the interference which is inconsistent with that party's failure to properly move, except that a losing party shall not be estopped with respect to any claims which correspond, or properly could have corresponded, to a count as to which that party was awarded a favorable judgment.

1. Claims 1-16 are rejected on the grounds of estoppel under rule 37 CFR 1.658(c).

The claims are drawn to a method of treating mucus secretion of a patient using botulinum toxin and wherein the mucus secretion is not a symptom of rhinorrhea.

Applicants argue that the estoppel under a 1.633(c) motion could not have been filed with the Board. Applicants state that Count 3 in the interference was expressly limited by the Board to rhinorrhea subject matter. It is contended that the rhinorrhea is a "particular and specialized type of mucus secretion and Sanders '605 patent . . . does not appear to disclose, claim or suggest treatment of any non-rhinorrhea mucus secretion."

Applicants arguments, file 1-14-04, have been considered but have not been found persuasive.

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The US Patent, in claim 5, states that the botulinum toxin was effective in the treatment of otitis media. It is well known in the art that one of the symptoms associated with otitis media is excessive mucus secretion in the reparatory tract and behind the eardrum. Note that claim states that the toxin was administered via a transtympanic means. Thus, claim 5 reads the treatment of mucus secretion that is "non-rhinorrhea." Thus, unlike applicants contention, Sanders does disclose a claim or suggest the treatment of a non-rhinorrhea mucus secretion. Accordingly, Claim 5 of the US Patent could have been the basis and additional count under 1.633(e)(1) and therefore Applicants are estopped.

Applicants have stated "a motion to add a count directed to treatment of a non-rhinorrhea mucus secretion would have been improper and/or could have been expected to have been denied by the Board as not related to the subject matter of the interference (treatment of sweat and treatment of rhinorrhea)." However, Applicants subject beliefs on how the Board would adjudicate such a matter is not the standard filing a 1.633(e) motion.

The rejection is maintained.

### **New Grounds For Rejections**

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(g)(1) during the course of an interference conducted under section 135 or section 291, another inventor involved therein establishes, to the extent permitted in section 104, that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or (2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

2. Claims 1-16 rejected under 35 U.S.C. 102(g) as being anticipated by Sanders et al.

The claims are drawn to method of treating mucus secretion using botulinum toxin, wherein the mucus secretion is not a result of rhinorrhea.

Sanders claims are drawn to a method of treating the Otis media comprising the transtympanic injection of botulinum toxin (See claim 5 of Sanders et al.). It is well known in the art that one of the symptoms associated with otitis media is excessive mucus secretion in the reparatory tract and behind the eardrum. Thus, the local administration of botulinum toxin via transtympanic route would necessarily treat the mucus secretion associated with otitis media. The reference claims botulinum toxin A-G can be used in the method (see claim 15). Further, the unit of toxin used in the procedure is between 10-100 units (see col. 5, lines 30-67). Although Sanders et al. does not claim the units disclosed, such a limitation is incorporated into the claims since the method involves the treatment of the disorders. When the claims are read in light of the specification, one is taught the treatment is achieved via 10-100 units of toxin.

3. Claims 1-16 rejected under 35 U.S.C. 102(b) as being anticipated by Sanders et al. and Tos (HNO).

The claims are drawn to method of treating mucus secretion using botulinum toxin, wherein the mucus secretion is not a result of rhinorrhea.

Sanders claims are drawn to a method of treating the Otis media comprising the transtympanic injection of botulinum toxin (See claim 5 of Sanders et al.). It is well known in the art

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that one of the symptoms associated with otitis media is excessive mucus secretion in the reparatory tract and behind the eardrum (see Tos reference abstract). Thus, the local administration of botulinum toxin via transtympanic route would necessarily treat the mucus secretion associated with otitis media. The reference claims botulinum toxin A-G can be used in the method (see claim 15). Further, the unit of toxin used in the procedure is between 10-100 units (see col. 5, lines 30-67).

Note that the reference is relevant as a 102(b) for the following reasons:

The benefit of the earlier filing date under 35 U.S.C. 120 of the parent application Serial No. 08/627,118 has been denied for claims 1-16 for the instant application. These claims in the instant continuation-in-part application recites a feature, i.e. "wherein the mucus secretion is **not** a symptom of rhinorrhea." This feature has been first introduced and adequately supported in the instant application 10/087,222 on page 6, and thus such claims are entitled only to the filing date of this application 10/087,222; In re Von Lagenhoven, 458 F.2d 132, 136, 173 USPQ 426, 429 (CCPA 1972) and Chromalloy American Corp. v. Alloy Surfaces Co., Inc., 339 F. Supp. 859, 874, 173 USPQ 295, 306 (D. Del. 1972).

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (703) 308-4001. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can normally be reached on (703)306-3220. The fax phone number of this group is (703) 308-4242.

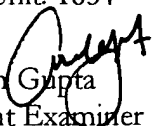
Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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Anish Gupta  
Patent Examiner

 2/23/04